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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,753	01/02/2002	Stanley Hazen	26473/04177	9142

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EXAMINER
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SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/039,753

**Applicant(s)**

HAZEN ET AL.

**Examiner**

David A. Saunders, PhD

**Art Unit**

1644

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-10, 23, 25-26, 28-29, 31-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 23, 25, 26, 28, 29 and 31-39 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Amendment of 9/6/06 has been entered. Claims 1-5, 7-10, 23, 25-26, 28-29 and 31-39 are pending and under examination.

The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The rejection of claims 1-10 23, 25-26, 28-29, 32 under 35 USC 112, 1st paragraph.

The 102(a) rejection of claim(s) 1, 3, 5-8, 10 based upon Zhang et al. The nature of the control subjects and of the types of blood leukocytes recited in amended claim 1 are supported by earlier filed US Prov. Applic. 60/293,432.

Applicant's amendment has necessitated the following new ground(s) of objection/rejection.

Claims 2, 28, 32, 35, 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In claim 2, line 2 "one or more populations of leukocytes" is improperly of broader scope than the "neutrophils and monocytes, or any combination thereof" recited in base claim 1.

In claim 28, at lines 2 and 5-6 "one or more populations of leukocytes" and at lines 3 and 4 "leukocytes" are improperly of broader scope than the "neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, sub-populations of monocytes, or any combination thereof" recited in base claim 23.

In claim 32, line 2 recitation of "one or more populations of the test subject's circulating leukocytes" is improperly of broader scope than the "neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, sub-populations of monocytes, or any combination thereof" recited in base claim 23.

In claim 35, lines 1-2 recitation of "one or more populations of the test subject's circulating leukocytes" is improperly of broader scope than the "neutrophils, monocytes, or a combination thereof " recited in base claim 34.

In claim 38, line 2 recitation of "one or more populations of the test subject's circulating leukocytes" is improperly of broader scope than the "neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, sub-populations of monocytes, or any combination thereof " recited in base claim 37.

Claims 1-5, 7-10, 23, 25-26, 28-29, 31-33, 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 1-2 and 10-11, "a test subject's risk of having" is confusing because, while a test subject might be at risk of "developing" (now cancelled) a disease, the subject either has or does not have the disease at the time the sample is drawn. Thus "a test subject's risk of having" is a senseless concept. It is suggested that applicant recite, respectively, --a test subject as having-- and --the test subject has--. Like considerations apply to claims 23, 31, 33.

In claim 23, the Markush group at lines 4-5 and 7-8 has an improper double inclusion of "sub-populations of neutrophils".

In claim 23, lines 11 and 12, "leukocytes" is of broader scope and thereby inconsistent with the recitation of "neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, sub-populations of monocytes, or any combination thereof " recited at lines 4-5 and 7-8.

In claim 26, line 8, "leukocytes" is of broader scope and thus inconsistent with the recitation of "neutrophils and monocytes, or any combination thereof " recited at line 5.

In claim 37, the Markush group at lines 5-7 has an improper double inclusion of "sub-populations of neutrophils".

The following rejections of record are maintained or modified as follows:

Art Unit: 1644

Claims 23,26,29,37,39 are rejected under 35 U.S.C. 102(a) as anticipated by Or, alternatively, under 35 U.S.C. 103(a) as obvious over Zhang et al (JAMA, 286, 2136, 2001,cited on Form 1449), for reasons of record in action of 8/17/06.

Zhang et al teach determining myeloperoxidase (MPO) mass per neutrophils (and thus a "normalized" value) by an ELISA ("immunological") assay. See para. spanning pp 2137-2138. Zhang et al also teach determining the MPO activity of lysed neutrophils, normalized as per mg of neutrophils protein or as per mg of blood. See p 2137, para spanning cols. 2-3. They compare levels of MPO (mass or activity) in patients having angiographically proven coronary atherosclerosis against a "select population" of control patients that showed no such diagnosed atherosclerosis. See p 2137, col. 1 and p 2141, col.1. They conclude that "MPO levels are associated with the presence angiographically proven coronary atherosclerosis." See p 2141, col.1, last para. Thus instant claim 23 is anticipated, since it claims the embodiment in which the method characterizes a patient as "having atherosclerotic cardiovascular disease". Zhang et al also teach that further studies should be conducted to evaluate "MPO as a predictor of future cardiac events in longitudinal studies". Thus instant claims 26 and 29 (as well as new claims 37 and 39) would have been obvious for the embodiment in which the claimed method characterizes a patient as at "risk of developing... atherosclerotic cardiovascular disease".

The rejection is maintained as proper, since the reference has a 102(a) date and has authors who are not inventors.

The reference has a 102(a) date because the instant claims are only accorded benefit of the instant filing date of 1/2/02. The examiner finds that the instant claims are broader than the invention supported by the last filed provisional application 60/283,432. The claims are thus properly rejected in accord with MPEP 201.11. Claims are deemed broader because of at least the following features:

1) the nature of the controls. In the '432 application the controls are limited to "healthy controls". There is no teaching of controls from the "general population" and there is no teaching of any "select population of controls" other than "healthy controls".

Art Unit: 1644

In amended claim 26, the nature of the "control subjects" has not been changed so that they are of the same scope as the "healthy controls" of Prov. Applic. 60/283,432.

2) the nature of the sample. In the '432 application the "leukocytes" are limited to neutrophils or monocytes (p 2, last para.). There is no teaching of any "sub-populations" of neutrophils, or sub-populations of monocytes, or of any "combinations" that would include these. In amended claim 23 and in new claim 37, applicant has included these "sub-populations". Applicant has urged that earlier filed US Prov. Applic. 60/259,340 teaches such sub-populations at p 9. While the examiner concurs that this teaching is present, it is not effective, because later filed Prov. Applic. 60/283,432 did not incorporate Prov. Applic. 60/259,340 by reference. Applicant wants to rely upon the disclosure of Prov. Applic. 60/259,340, in order to obtain an effective filing date of 1/2/01 for overcoming the Zhang et al reference; it is to be noted, however, that this reference fails to disclose blood, serum or plasma samples. Thus, Prov. Applic. 60/259,340 would fail to support instant claims encompassing the use of blood, serum or plasma samples.

Applicant's arguments filed 9/6/06 have been fully considered but they are not persuasive for the above reasons.

No new reference has been cited; this action is thus made FINAL.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1644

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 11/15/06 DAS

A handwritten signature in black ink, reading "David A. Saunders". The signature is fluid and cursive, with the first name "David" and last name "Saunders" clearly distinguishable.

DAVID A. SAUNDERS  
PRIMARY EXAMINER